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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,956	02/08/2001	Peter James Woolf	A0000133-01-CA	5820

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,956	WOOLF ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,29,33 and 40-45* is/are rejected.

7)☒ Claim(s) *28,30-32 and 34-39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment and request for reconsideration in the communication filed on 2/28/05, is acknowledged and the amendments entered.

Applicant's arguments in response to the previous Office action have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are reiterated from the previous Office action, mailed 11/17/04, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

2. The amendment to the title filed 2/28/05 is not in complete compliance with 37 CFR 1.121 because of the following reason(s):

The amendment deletes the previous title of the specification and replaced with a new title. However, the new title does not have markings to show changes. 37 CFR 1.121(b) states that amendment to the title "is considered for amendment purposes requires to be an amendment of a paragraph," and requires "the full text of any replacement paragraph with markings to show all the changes relative to the previous version of the paragraph." An amendment to the title in complete compliance with 37 CFR 1.121 is required.

Nevertheless, the amendment to the title overcomes the objection thereto set forth in the previous Office action mailed 11/17/04.

Declaration

3. The declaration filed 8/24/01is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because non-initialed and non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The citizenship of inventor Yixin Wang is changed in the declaration, but the alteration is not initialed and dated.

Specification

4. The specification is objected to because of the following:

It is noted that trademarks are used in this application, such as GENECHIP™ on page 7 and elsewhere. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections-35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-22 and 42-44 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is reiterated from the previous Office action mailed 11/17/04.

In the preamble of independent claims 1 and 9, the practice of the claims may be interpreted as being directed to a plurality of "biological cells". See, for example, line 2 of claim 1. However, in the actual method steps, such as lines 3-10 of instant claim 1, there is no corresponding plural "cells" limitation. In line 3 of instant claim 1, the expression data is described as being "cell-derived", which at best only cites a single cell. It may be assumed that multiple cells are meant, however, and the requirement for such an assumption supports this rejection that the claims are not clear and concise as required by 35 U.S.C. 112, second paragraph. Claims that are dependent from claims 1 or 9 also contain this unclarity due to their dependence. Clarification via clearer claim wording is requested.

Applicants' arguments filed 2/28/05 have been fully considered but they are not persuasive. Applicants, on the one hand, argue that "one of ordinary skill in the art while reading the claims would understand that cell-derived samples refers to one or more cells" (underling added by the examiner), indicating an alternative "one or more cells." On the other hand, applicants argue that "the phrase 'cell-derived' is an adjective meaning that the samples are derived from multiple cells" (underling added by the examiner), indicating "multiple cells" only. Applicants further provide Humpherys et al. (PNAS, Vol. 99, page 12889, 2002) (Exhibit A) and argue that "the adjective 'cell-mediated' refers to multiple cells." Applicants' argument that the phrase "cell-mediated" in Exhibit A (page 12889 of Humpherys et al.) means "multiple cells" is not disputed. While applicants argument apparently clarifies that "cell-derived" can mean multiple cells, it raises unclarity as to the meaning of "cell-derived". It is not clear whether "cell-derived" means "one or more cells" or just "multiple cells." Clarification via clearer claim wording is suggested.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 , 9, 16, 23-27, 29, 33, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramm et al. (P/N 6,345,115) in view of Agrafiotis et al. (P/N 6,421,612).

This rejection is reiterated from the previous Office action mailed 11/17/04. See pages 3-7 therein.

Applicant's arguments filed 2/28/05 have been fully considered but they are not persuasive. Applicants' argument is essentially on the ground that Agrafiotis et al. do not teach or suggest applying a set of heuristic rules and determination of confidence level. This is not found persuasive. As set forth in the previous Office action, page 6, in Agrafiotis et al., the most important features of molecules are also analyzed via principle component analysis, scaling, etc. as described in column 21, lines 50-54, which is reasonably a heuristic rule application. Applicants did not argue against this view. As to determination of confidence level, as set forth in the previous Office action, page 5, in column 11, lines 1-15, Ramm et al. described modeling and correcting measurements to result in low error variation in order to achieve acceptable accuracy in quantifying data. This low error variation evaluation is an evaluation of the confidence level of predicted values as required in the instant claim 1. Applicants did not provide arguments on this point. Therefore, the combination of Ramm et al. and Agrafiotis et al. discloses the application of heuristic rules and determination of confidence level.

Claim Objections

9. Claims 28, 30-32, and 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.**

12. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

Ardin H. Marschel 6/12/05

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER